IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: | Andersen, et al | Conf. No.: | 2890 |
| Application No.: | USSN 10/509,980 | Docket No.: | 60275-USA |
| Filed: | January 3, 2005 | Examiner: | Sheikh, Humera N. |
| Art Unit: | 1615 | | |

For: POLYSACCHARIDE CAPSULES AND METHODS OF PREPARATION

**Declaration Under 37 C.F.R. § 1.132**

I, Dr. Olav Gåserød, hereby declare as follows:

## I. Background

A. I received a Ph.D degree in Biopolymer Chemistry from the Norwegian University of Science and Technology, Trondheim, Norway in 1998 with a focus on microcapsules containing alginate and chitosan. I have been employed since September, 1998, by FMC Corporation, primarily in the area of alginate chemistry and technology. I am a technical manager, and my current title is Team Leader – Alginate Commercial Technology.

B. I am an inventor listed on USSN 10/509,980 (the '980 application), and I have been working in the field of soft capsules since 2001.

C. I am familiar with the rejections set forth in the Office Action dated June 23, 2010. The following comparative testing was carried out by me and/or under my direction.

## II. Testing

A. The following testing was performed in order to evaluate the differences in functionality between using a water in oil ("W/O") emulsion as compared to an oil in water ("O/W") emulsion in the process described in the '980 application. The formulations prepared and tested are set forth immediately below.



30.08.2010

| | Ingredient amount (g) | |
|---|---|---|
| | Test A | Test B |
| **Emulsions** | | |
| Water | 10 | 8 |
| CaCl2 2H2O | 15 | 5 |
| Emulsifier* | 0.5 | 0.5 |
| Olive oil | 74.5 | 86.5 |
| Total | 102 | 100 |
| | | |
| **Alginate bath** | | |
| Alginate (Protanal LF CAP 5/60) | 10.5 | 10.5 |
| Water | 517.5 | 517.5 |
| Tween 20** | 0.6 | 0.6 |
| Ethanol | 72 | 72 |
| | | |

* Span 80 was used in the w/o emulsions, and Tween 20 was used in the o/w emulsions
** Tween 20 was added only to the alginate bath receiving the w/o emulsion

B. Both Test A and Test B was formulated as W/O and O/W emulsions - 4 emulsions in total. The same alginate bath was used to receive all the emulsions, except for the Tween 20 which was added only to the bath receiving the W/O emulsion. The emulsions were made by dissolving the calcium chloride in the water. The emulsifier was dissolved in the water for the O/W emulsions and in the oil for the W/O emulsions. The discontinuous phase was then added slowly to the continuous phase while mixing with a homogenizer (Ultra Thurrax) under similar conditions for each emulsion type.

The W/O emulsions had a viscosity upon visual observation that was similar to the oil, and the O/W emulsions had a viscosity similar to thick mayonnaise.

C. The alginate baths were prepared by adding the alginate to a blend of the water and ethanol while mixing with a propeller stirrer. The Tween 20 was added to the alginate bath receiving the W/O emulsions and mixed therein. The Tween 20 and ethanol in the alginate solution was added to reduce surface tension and adjust the density of the bath.

D. The W/O emulsions were added to the alginate bath by dropping from a pipette. The droplets did not immediately break through the surface of the bath, but spread on the surface of the bath. As a result, the fragments were irregularly shaped and did not form proper seamless capsules.

E. The O/W emulsions were added to the alginate bath by extruding the emulsion using a plastic pipette and cutting off fragments of the emulsion using a scalpel. The fragments acted more like a solid (than the W/O droplets) and readily entered and submerged into the bath. As a result, the alginate shell



30.08.2010

started forming immediately and became 1.7 mm thick after about 28 min (Test A/high calcium), and 0.9 mm thick after 25 minutes (Test B/low calcium). The O/W emulsion thus formed proper seamless capsules having an even surface and good, consistent shape.

F. Conclusion – The O/W emulsions were unexpectedly found to be significantly more suitable to forming consistently good capsules than the W/O emulsions in a side-by-side comparison.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the application or any patent issued thereon

Dated: 30.08.2010

Signed: Olav Gåserød

Print Name: Dr. Olav Gåserød